DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 21, 2014

Tornier, OrthoHelix Surgical Designs, Inc.
Mr. Brian Hockett
Director of Research and Development
1065 Medina Road, Suite 500
Medina, Ohio 44256

Re: K141004
Trade/Device Name: Intraosseous Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: August 4, 2014
Received: August 6, 2014

Dear Mr. Brian Hockett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number TBD: K141004

Device Name: Intraosseous Fixation System

Indications for Use:

The Intraosseous Fixation System is indicated to stabilize and aid in fixation of fractures, fusions, and osteotomies of the phalanges.

Prescription Use ___X____ AND/OR Over-The-Counter-Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) SUMMARY

Submitter Information

Submitter's Name:	OrthoHelix Surgical Designs, Inc.
Address:	1065 Medina Rd, Suite 500 Medina, Ohio 44256
Telephone Number:	330-869-9562
Fax Number:	330-247-1598
Prepared By:	Amanda Martin and Simon Sjovold
Contact Person:	Brian Hockett
Date Prepared:	8/20/2014

Device Information

Trade Name:	Intraosseous Fixation System
Common Name:	Fixation Device
Classification Name:	Pin, Fixation, Smooth
Device Classification:	Pin, Fixation, Smooth (Class II per 21 CFR 888.3040) Panel: Orthopedic, Product Code: HTY
Material Composition:	Titanium Alloy and Polyetheretherketone (PEEK)
Device Description:	The Intraosseous Fixation System consists of various size implants to stabilize and aid in the fixation of fracture, fusions, and osteotomies of the phalanges. The implants are offered in different lengths and diameters. All implants are manufactured from implant grade titanium alloy or PEEK.
Intended Use:	The Intraosseous Fixation System is intended to stabilize and aid in the fixation of fractures, fusions, and osteotomies of phalanges.
Substantial Equivalence:	The Intraosseous Fixation System is substantially equivalent to the OrthoHelix Intraosseous Fixation System (K120165), MMI Smart Toe (K070598), OrthoHelix MaxLock Extreme Extremity Plating System with Variable Angle Technology (K100618), Extremity Medical HammerFiX IP Fusion System (K133636), Bioretec ActivaPin (K061164) and Arthrex Bio-Pin (K050259). Mechanical 4 point bend, axial pull-out, insertion and removal torque and torque to failure testing were performed to establish substantial equivalence. No new issues of safety and effectiveness have been raised.